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NOTICE OF ALLOWANCE AND FEE(S) DUE

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7590

01/04/2011

King & Spalding LLP

EXAMINER GOON, SCARLETT Y ART UNIT PAPER NUMBER

1623 DATE MAILED: 01/04/2011

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/581,571 | 07/13/2007 | Glenn D. Prestwich | 67934-8006.US00 | 6987 |

TITLE OF INVENTION: MODIFIED MACROMOLESCULES AND ASSOCIATED METHODS OF SYNTHESIS AND USE

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | \$0 | \$1810 | 04/04/2011 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current **SMALL ENTITY status:**

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II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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| maintenance fee notifica CURRENT CORRESPOND | Fee par | e(s) Transmittal. Thi | s certifi l paper, | cate cannot be used for such as an assignment | domestic mailings of the or any other accompanying it or formal drawing, must | | |
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| 79975 King & Spaldin P.O. Box 889 Belmont, CA 94 | _ | /2011 | I h Sta ado trai | Cer ereby certify that the tes Postal Service we dressed to the Mail ansmitted to the USP | t ificate is Fee(s rith suff Stop I ΓΟ (571 | of Mailing or Transn) Transmittal is being icient postage for first SSUE FEE address) 273-2885, on the da | nission deposited with the United class mail in an envelope above, or being facsimile te indicated below. |
| | | | | | | | (Depositor's name) |
| | | | _ | | | | (Signature) |
| | | | | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | R | ATTOR | RNEY DOCKET NO. | CONFIRMATION NO. |
| 10/581,571 | 07/13/2007 | | Glenn D. Prestwich | | 679 | 934-8006.US00 | 6987 |
| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUI | o occ | TOTAL FEE(S) DUE | DATE DUE |
| nonprovisional | NO NO | \$1510 | \$300 | \$0 | 3135 | \$1810 | 04/04/2011 |
| EXAM | | ART UNIT | CLASS-SUBCLASS | 7 | | \$1010 | 04/04/2011 |
| GOON, SC | ARLETT Y | 1623 | 514-054000 | _ | J | | |
| "Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A PLEASE NOTE: Unl | ND RESIDENCE DATA less an assignee is identi h in 37 CFR 3.11. Comp | "Indication form ed. Use of a Customer A TO BE PRINTED ON 7 ified below, no assignee | (1) the names of up to a gents OR, alternat (2) the name of a sing registered attorney or 2 registered patent attained, no name will be THE PATENT (print or ty data will appear on the pT a substitute for filing an (B) RESIDENCE: (CIT | gle firm (having as a agent) and the namorneys or agents. If the printed. Type) patent. If an assignment. | members of up no name | er a 2 to to e is 3 | cument has been filed for |
| | | 4l permitted) | o. Payment of Fee(s): (Ple A check is enclosed. Payment by credit ca The Director is hereboverpayment, to Dep | ease first reapply ar ard. Form PTO-2038 by authorized to char | is attac | iously paid issue fee s ched. equired fee(s), any def | |
| | s SMALL ENTITY statu | is. See 37 CFR 1.27. | ☐ b. Applicant is no los | nger claiming SMAI | L ENT | TTY status. See 37 CF | R 1.27(g)(2). |
| interest as shown by the | records of the United Sta | tes Patent and Trademark | Office. | ше аррисапі; а геді | siered a | tionney or agent; or the | e assignee or other party in |
| Authorized Signature | | | Date | | | | |
| Typed or printed name | | | Registration No | | | | |
| an application Confident | tiality is governed by 35 application form to the tons for reducing this but irginia 22313-1450. DC | U.S.C. 122 and 37 CFR | 1.14 This collection is es | stimated to take 12 r | ninutes | to complete including | by the USPTO to process) g gathering, preparing, and the you require to complete rtment of Commerce, P.O. or Patents, P.O. Box 1450, |

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

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| 10/581,571 | 07/13/2007 | Glenn D. Prestwich | 67934-8006.US00 6987 | | |
| 79975 7: | 590 01/04/2011 | | EXAMINER | | |
| King & Spalding | LLP | GOON, SC. | ARLETT Y | | |
| P.O. Box 889 | | | ART UNIT | PAPER NUMBER | |
| Belmont, CA 9400 | 02-0889 | | 1623 | | |
| | | | DATE MAILED: 01/04/2011 | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 527 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 527 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

| | Application No. | Applicant(s) | |
|---|--|--|----|
| | 10/581,571 | PRESTWICH ET AL. | |
| Notice of Allowability | Examiner | Art Unit | |
| | SCARLETT COON | 1600 | |
| | SCARLETT GOON | 1623 | |
| The MAILING DATE of this communication apperature All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSEI or other appropriate com IGHTS. This application | D in this application. If not included imunication will be mailed in due course. TH | |
| 1. \boxtimes This communication is responsive to <u>22 November 2010</u> . | | | |
| 2. \boxtimes The allowed claim(s) is/are $\underline{4,5,7,51,52,200,224-226,229,2}$ | <u>230,234-237,239,240 and </u> | <u>242-244</u> . | |
| 3. Acknowledgment is made of a claim for foreign priority unally All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority do | e been received. e been received in Applica | ation No | ne |
| International Bureau (PCT Rule 17.2(a)). | | | |
| * Certified copies not received: | | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | | file a reply complying with the requirements | |
| 4. A SUBSTITUTE OATH OR DECLARATION must be subminformal PATENT APPLICATION (PTO-152) which give | | | |
| 5. CORRECTED DRAWINGS (as "replacement sheets") mus | st be submitted. | | |
| (a) I including changes required by the Notice of Draftspers | on's Patent Drawing Rev | riew (PTO-948) attached | |
| 1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date | | | |
| (b) ☐ including changes required by the attached Examiner's Paper No./Mail Date | s Amendment / Commen | t or in the Office action of | |
| Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t | | | |
| 6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT | | | |
| | | | |
| Attachment(s) 1. ☑ Notice of References Cited (PTO-892) | 5. ☐ Notice o | f Informal Patent Application | |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948) | | Summary (PTO-413), | |
| 3. Information Disclosure Statements (PTO/SB/08), | Paper N 7. ⊠ Examine | lo./Mail Date r's Amendment/Comment | |
| Paper No./Mail Date 4. | 8. 🛛 Examine | r's Statement of Reasons for Allowance | |
| of Biological Material | 9. 🔲 Other | <u>.</u> | |
| /SCARLETT GOON/ | /Shaojia Anr | na Jiang/ | |
| Examiner, Art Unit 1623 | Supervisory | Patent Examiner, Art Unit 1623 | |
| | | | |

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On 15 December 2010, a proposed amendment in condition for allowance was discussed with Ms. Susan T. Evans, Applicants' attorney, in a telephone interview.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Susan T. Evans on 15 December 2010.

The application has been amended as follows:

- Claims 4, 7 and 224 have been amended, as listed below.
- Claim 2 has been cancelled, as listed below.
- Note: For those claims that are neither amended nor canceled as indicated in this Examiner's Amendment, see the amendment filed on 22 November 2010.

2. (Cancelled)

4. (Currently Amended) The modified-glycosaminoglycan of claim 225, wherein "GAG-O-" represents the residue of substituted hydroxyl group that is a primary C-6

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hydroxyl group contained within an N-acetyl-glucosamine residue present in the hyaluronan.

7. (Currently Amended) The modified-glycosaminoglycan of claim 224, wherein "GAG-O-" represents the residue of a substituted hydroxyl group that is a primary C-6 hydroxyl group contained within a non-uronic acid sugar component of a repeating disaccharide of the glycosaminoglycan.

224. (Currently Amended) A modified glycosaminoglycan corresponding to the structure:

wherein

"GAG" is a glycosaminoglycan <u>selected from the group consisting of chondroitin</u>, <u>chondroitin sulfate</u>, <u>dermatan</u>, <u>dermatan sulfate</u>, <u>heparin</u>, <u>heparan sulfate</u>, <u>and</u> <u>hyaluronan</u>, <u>wherein the GAG possessing possesses</u> a plurality of hydroxyl groups,

"GAG-O" represents a residue of a <u>substituted</u> hydroxyl group on the glycosaminoglycan,

n is 2 or 3, and

0.1% to 40% of the glycosaminoglycan's primary hydroxyl groups are substituted with -CH₂C(O)NH-NH-C(O)(CH₂)_n-SH.

DETAILED ACTION

Applicants' Amendment and Remarks filed on 22 November 2010, in which claims 1, 3, 6, 8-50, 53-199, 201-223, 227, 228, 231-233, 238, 241, 245 and 246 were cancelled, and claims 2, 4, 5, 7, 51, 52, 200, 224, 230, 236, 239, 242 and 244 were amended to change the breadth and scope of the claims, is acknowledged.

Claims 4, 5, 7, 51, 52, 200, 224-226, 229, 230, 234-237, 239, 240 and 242-244 are pending in the instant application and are found to be allowable.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The instantly claimed compounds and compositions are not seen to be taught or fairly suggested in the prior art, as discussed below.

Applicants' amendment and arguments, filed 22 November 2010, with respect to the rejection of claim 236 made under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been fully considered and are persuasive as the claim has been amended to clearly indicate what is meant by gelatin-DTPH. Additionally, the structure of gelatin-DTPH is shown in Figure 8 of the instant application, and a journal article publication by Mironov *et al.* (p. 2056, column 2; p.

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2057, Figure 2; PTO-892, Ref. U) clearly supports gelatin-DTPH to be the abbreviated form of the full chemical name recited in claim 236.

Applicants' amendment and arguments, filed 22 November 2010, with respect to the rejection of claims 1-10, 24, 25, 51-53, 200, 227, 228, 239, 240 and 242-244 made under 35 USC § 112, first paragraph, as failing to comply with the written description requirement, have been fully considered and are persuasive because the claims have been cancelled and/or the limitation that was deemed to insert new matter into the claims has been deleted from the claims.

Applicants' amendment and arguments, filed 22 November 2010, and the Examiner's amendment above, with respect to the rejection of claims 1, 7-10, 24, 25, 53, 200, 227, 228, 239, 240 and 242-244 made under 35 USC § 103(a) as being unpatentable over PG Pub No. US 2003/0087877 A1 to Calias *et al.*, in view of U.S. Patent No. 5,874,417 to Prestwich *et al.*, have been fully considered and are persuasive. Claims 1, 8-10, 24, 25, 53, 227 and 228 have been cancelled. Claims 7, 200, 239, 240 and 242-244 have been amended to be dependent from allowable claim 224. These rejections have been withdrawn.

In view of the Examiner's amendment above, the instantly claimed modified glycosaminoglycan corresponding to the structure as recited in claim 224, and compositions comprising the modified glycosaminoglycan as recited in claim 224, is non-obvious over the teachings of the prior art. Although the prior art discloses conjugation of hydrazide linkers to glycosaminoglycans such as hyaluronic acid, one of

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ordinary skill in the art would have no motivation to further insert a methylene group between the hydrazide linker and the functional group on GAG, particularly since the prior art teaches that the reactive moieties are the carboxylic acid residue present on hyaluronic acid (or other GAG) with the amine moiety present on a dihydrazide structure.

In view of the cancellation of claims 1-3, 6, 8-50, 53-199, 201-223, 227, 228, 231-233, 238, 241, 245 and 246, all rejections made with respect to claims 1-3, 6, 8-50, 53-199, 201-223, 227, 228, 231-233, 238, 241, 245 and 246 in the previous Office Actions are withdrawn.

The modified glycosaminoglycan corresponding to the structure as recited in instant claim 224, and compositions comprising the modified glycososaminoglycan as recited in claim 224, are disclosed in the instant Specification. For example, support for the claimed modified glycosaminoglycan corresponding to the structure as recited in instant claim 224 can be found on p. 46-47 of the Specification as filed, and the original claims, and support for the claimed compositions can be found on p. 51 of the Specification as filed, and the original claims. Examples for the synthesis of the modified glycosaminoglycan and their use for supporting the growth of cells is further disclosed. Hence, the instantly claimed modified glycosaminoglycan corresponding to the structure as recited in instant claim 224, and compositions comprising the modified

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glycososaminoglycan as recited in claim 224, are enabled and have sufficient written description in the Specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/ Supervisory Patent Examiner, Art Unit 1623 /SCARLETT GOON/ Examiner Art Unit 1623